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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/492,763 01/27/00 MASATSUJI

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HM22/0301

EXAMINER

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KIM, V

ART UNIT

PAPER NUMBER

1614

DATE MAILED:

03/01/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/492,763	MASATSUJI ET AL.	
	Examiner Vickie Y. Kim	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.  
 4a) Of the above claim(s) 7,8 and 10-15 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1-6 and 9 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claims \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- 15) Notice of References Cited (PTO-892)      18) Interview Summary (PTO-413) Paper No(s). \_\_\_\_.  
 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)      19) Notice of Informal Patent Application (PTO-152)  
 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ .      20) Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in Japan on Jan.26, 1999. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter. However, Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

### ***Election/Restrictions***

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-10, drawn to a dermal agent comprising a therapeutically effective amount of an ascorbic acid derivative , classified in class 514, subclass 99.
  - II. Claims 11-13, drawn to a poultice comprising a hydrophilic resin and the dermal agent, classified in class 424, subclass 485.
  - III. Claims 14, drawn to a composition comprising tretinoin and an ascorbic acid derivative , classified in class 514, subclass 560.
- IV. Claim 15, drawn to a method, classified in class 514, subclass 474.

The inventions are distinct, each from the other because of the following reasons:

6. Inventions I and II (or III) are unrelated. Inventions are distinct because they have different modes of operation (or different modes, effects, respectively) (MPEP § 806.04, MPEP § 808.01). Inventions I-III and IV are related as product and process of use. The inventions can

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be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). For example, the combination of ascorbic acid and tretinoin is used in a materially different use such as acne and other proliferative skin diseases: see US5,643,585. Furthermore, the irritation of tretinoin could be relieved by the method which uses materially different product such as zinc salt of retinoic acid see US 4,214,000. A reference which anticipates each invention would not render any other invention obvious, absent ancillary art.

7. In addition, because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

8. Claims 7-10 are generic to a plurality of disclosed patentably distinct species comprising various derivatives of ascorbic acid. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. During a telephone conversation with Mr. Claymont on Feb. 22, 2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-6 and 7-10 including election of species, where claim 9(zinc salt of ascorbic acid phosphate) among claims

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7-10 are elected. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-8 and 10-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claims 1-6 and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Suzuki et al (EP884321).

The claims read on a dermal agent comprising agent comprising a therapeutically effective amount of a zinc salt of ascorbic acid derivative represented by the formula (3).

EP'321 teach a dermal composition comprising ascorbic acid 2-phosphate zinc salt; see example 3, page 6.

All the critical elements required by the instant claims are met by the cited references.

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It is noted that a recitation of the intended use of the claimed invention, in case of the claimed invention is directed to the composition claims, must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

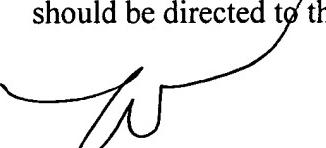
Thus the claimed subject matter is not patentably distinct over the prior art.

***Conclusion***

13. Claims 1-6 and 9 are elected and considered for the examination.
14. Claims 7-8 and 10-15 are withdrawn form consideration.
15. The claims 1-6 and 9 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is (703) 305-1675 (Tuesday-Friday: 8AM-6:30PM) and Fax number is (703) 308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Vickie Kim,  
Patent examiner  
February 22, 2001

  
William Jarvis  
Primary examiner  
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